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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,920	05/11/2007	Shigeru Nakajima	125192.00401	7896

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EXAMINER	
MUKHOPADHYAY, BHASKAR	
ART UNIT	**PAPER NUMBER**
1787	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,920	NAKAJIMA ET AL.	
	Examiner	Art Unit	
	BHASKAR MUKHOPADHYAY	1787	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments and amendment filed dated 4/27/2010 overcomes the rejections of record, however, the new grounds of rejection as set forth below are necessitated by applicants' amendment and therefore the following action is **final.**

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 12-17, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. Claim 12 recites the phrase "therapeutically effective amount". But there is no support for such phrase in the specification.

5. Regarding claim 12, while there is support to recite “a material” comprising protein with histidine content, there does not appear to be support to recite "composition comprising".

6. Regarding claim 13, while there is support to recite "material comprising 12,000-20,000 mg histidine", there does not appear to be support to recite "composition comprising 12-20% histidine".

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 12- 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Regarding claim 12, the scope of the claim is confusing given that the claim is drawn to composition obtained by the recited steps, however, the steps result in histidine protein from fish and not composition.

10. Claim 17 recites the phrase “composition is obtained ". However, the steps can provide histidine enriched protein from fish which is one of the ingredients in the composition. So the claim is indefinite.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action.

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

a. Determining the scope and contents of the prior art.
b. Ascertaining the differences between the prior art and the claims at issue.
c. Resolving the level of ordinary skill in the pertinent art.
d. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 12, 13, 15, 16, are rejected under 35 U.S.C. 103 (a) as being unpatentable over Nakajima S et al., (NPL: Nakajima S et al., J Jpn. Soc. Nutr. Food Sci. 53: 207-214, 2000) in view of Henkin , USPN 3867539 and further in view of the

evidence given by NPL " Histidine induced Lipolysis"(Yoshimatsu, H et al., Eur J Clin Invest. 32:236-241,2002).

14. Regarding claims 12, 13,15, and 16, Nakajima S et al. teach about a material for processed food for weight reduction diets (Abstract, e.g. 'obesity'), comprising protein with a high histidine content (Abstract, e.g. 'histidine is enriched in tuna and bonito'), extracted from fish (Abstract, e.g. 'histidine enriched protein'; Table3, e.g. "Name of food), to maintain body protein and histidine has suppressive effect of food intake by activating histaminergic neuron (Abstract, e.g. 'intake of histidine in 64 male and female students and Fig 2).

It is well known, as evidenced by NPL "Histidine Induced Lipolysis" that histidine induces lioplysis (Title and Abstract) and therefore inherently breaks down lipids thereby reducing body fat.

Nakajima S et al. teach about a dietary processed food, processed using the material for processed food for weight reduction diet (Abstract, e.g. 'obesity, and 'orally administered histidine- enriched protein on food intake' and in page 213, Table 3, e.g. one example, Food as 'Yellow tuna' 87 mg His / g protein).

Nakajima S et al., however, do not disclose a composition comprising therapeutically effective amount of protein or in the form of a tablet and capsule.

Henkin teaches about therapeutically effective amount of histidine 1 to 32 grams per day (col 1, line 51) is effective for weight reduction without any undesirable side effects (col 1, line 62) and can be used in the composition as a tablet, capsule etc.

(col 1, lines 35-40) in human subjects (col 2, line 9). The motivation is to use the disclosed therapeutic amount of histidine (Henkin, col 1, line 52) in order to achieve anorexigenic or appetite suppressing effect without producing the undesirable side effects compared to other agents (col 1, lines 18-24).

It is obvious that one of ordinary skill in the art at the time of invention would use equivalent amount of protein extract from fish (Nakajima et al., page 213, Table 3, e.g. one example, Food as 'Yellow tuna' 87 mg His / g protein) to obtain the disclosed therapeutic amount of Histidine (Henkin, col 1, line 52) in order to achieve anorexigenic or appetite suppressing effect without producing the undesirable side effects compared to other agents (col 1, lines 18-24).

It would have been obvious to one of ordinary skill in the art at the time of invention to include the teaching of NPL " Histidine induced Lipolysis", Henkin into Nakajima S et al. One of ordinary skill in the art would have been motivated to use histidine in the form of the protein extract from fish which contains the disclosed therapeutic amount of histidine (Henkin, col 1, line 52) in order to get an anorexigenic or appetite suppressing effect without producing the undesirable side effects compared to other agents (Henkin, col 1, lines 18-24).

15. Claims 14, and 17, are rejected under 35 U.S.C. 103 (a) as being unpatentable over Nakajima S et al., (NPL: Nakajima S et al., J Jpn. Soc. Nutr. Food Sci. 53: 207-214, 2000) in view of Henkin, USPN 3867539 and NPL " Histidine induced Lipolysis" as applied to claim 12, and further in view of Ogura T et al., (S63-101370).

16. Regarding claim 14, Nakajima S et al. in view of Henkin, teach about therapeutically effective amount of histidine 1 to 32 grams per day (col 1, line 51), but do not teach about wt percent of histidine is contained in Bonito.

Ogura T et al. teach about histidine in the amount of 8-12% (under the heading, 'problems to be solved by this invention', 1st paragraph, a) bonito broth contains natural His in the amount of 8-12% of its solids). The motivation is to use bonito broth which contains the daily nutritional need of L-histidine and at a cheaper cost L-histidine hydrochloride can be purified from unused bonito broth extract waste (Ogura et al., page 1, under "Purpose of invention").

It would have been obvious to one of ordinary skill in the art at the time of invention to include the teaching of Ogura T et al. into Nakajima et al. One of ordinary skill in the art would have been motivated to purify histidine from unused bonito broth extract waste (Ogura et al., page 1, under "Purpose of invention").

17. Regarding claim 17, Nakajima S et al in view of NPL " Histidine induced Lipolysis" and Henkin teach about histidine enriched protein and source is from Bonito (Abstract, e.g. 'histidine is enriched in tuna and bonito').

Nakajima S et al do not teach about extraction from fish in powder form and deodorizing.

Ogura T et al. teach about activated charcoal treatment to decolorize and yield a histidine product in crystal form to meet the standard for pharmaceutical ingredients (in

Example 1, 2nd paragraph, e.g. 'The crystal purity of the crystals was 95% or more. The crystals were dissolved again and, upon decolorization with activated charcoal, recrystallized, yielding a product that met the standard for "L-histidine hydrochloride" in the Japanese standards for Pharmaceutical ingredients.). It is obvious that the crystal which is precipitated in pure form is known as L- Histidine hydrochloride monohydrate which is in the form of white crystalline powder as the product to be used. It is also obvious that the charcoal treatment not only decolorizes, but also deodorizes and gets rid of fishy flavor to meet the requirement of histidine in pure form.

It would have been obvious to one of ordinary skill in the art to include the teaching of Ogura T et al. into Nakajima S et al. in view of NPL " Histidine induced Lipolysis" and Henkin. One of ordinary skill in the art would have been motivated to use active charcoal treated pure histidine which is free from odor and a flavor of said extract from where it was purified to have its use in any kind of food, both vegetarian and non vegetarian, as weight reduction diet composition, without fishy smell.

18. Regarding claim 17, although Nakajima S et al. in view of Ogura T et al. do not teach about "electrodialysis" and "Reverse Osmosis" , it is noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process", *In re Thorpe*, 777 F.2d 695,

698, 227 USPQ 964, 966 (Fed. Cir.1985). Further, "although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product", *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). See MPEP 2113.

Therefore, absent evidence of criticality regarding the presently claimed process and given that Nakajima S et al. in view of Henkin, NPL " Histidine induced Lipolysis", and Ogura T meet the requirements of the claimed material, Nakajima et al. clearly meet the requirements of present claim 17.

Response to Argument

19. Applicants' arguments filed 4/27/10 have been fully considered but they are not persuasive.

Applicants argue on page 5, paragraphs 1, and 2, that Nakajima et al., can not meet all the claimed elements and Nakajima et al., is silent to the effects of histidine on reducing fat (page 5, paragraph 2, line 1) in the amended claim 12. However, Nakajima et al. is now used as primary reference in combination with Henkin to teach therapeutic amount of "Histidine" and NPL " Histidine induced Lipolysis" to teach reduction of fat by histidine for the 103 (a) rejection in present office action.

20. Applicants argue on page 6, lines 1-3 that " Ogura is silent to the use of reverse osmosis membrane or the use of electrodialysis. In fact, Ogura expressly teaches away

from the step of desalinating using electrodialysis". However, although Nakajima S et al. in view of Henkin, NPL " Histidine induced Lipolysis", and Ogura T do not teach about "electrodialysis" and "Reverse Osmosis" , it is noted that "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process", *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir.1985). Further, "although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product", *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). See MPEP 2113.

Therefore, absent evidence of criticality regarding the presently claimed process and given that Nakajima S et al. in view of Henkin, NPL " Histidine induced Lipolysis", and Ogura T meet the requirements of the claimed material, Nakajima et al. clearly meet the requirements of present claim 17.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

22. A shortened statutory period for reply to this non- final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. Any inquiry concerning the communication or earlier communications from the examiner should be directed to Bhaskar Mukhopadhyay whose telephone number is (571)-270-1139.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571)-272- 1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B.M. /
Patent Examiner, Art Unit 1787

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1787